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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Telovital's 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the **clue medical** and **clue medical BASIC** is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

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Date Prepared: October 10, 2008

Proposed Class: II

Proprietary Name: **clue medical** and **clue medical BASIC** Telemedical Systems

Common Name: Electrocardiograph

Classification Name: Electrocardiograph

Regulation Number: 21 CFR 870.2340, 21 CFR 870.2920

Product Codes: DPS, DXH

Predicate Device(s):

	Device Name	Procode	Common Name	Class
K072353	Portable ECScope, DyAnsis Corp.	DPS	Electrocardiograph	Class II
K060766	HCG Portable ECG Monitor, Omron Healthcare	DPS	Electrocardiograph	Class II

K050670	Sensor mobile SM 100 VITAPHONE	DXH	transmitters and receivers, electrocardiograph, telephone	Class II

Indication for Use

The **clue medical** and **clue medical BASIC** are handheld battery operated single channel electrocardiographs intended for recording and transmitting ECG data by patients who are concerned about their heart rhythm. The **clue medical** and **clue medical BASIC** allow the patient to record their ECG data into the device memory and transmit it for display by healthcare professionals.

Specifically, the **clue medical** and **clue medical BASIC** are intended for patients that are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:
Skipped beats
Pounding heart (palpitations)
History of arrhythmia

The **clue medical** and **clue medical BASIC** ECG data is intended to be used by a licensed health care practitioner. These measurements are not intended for any specific clinical diagnosis. The clinical significance must be determined by the physician.

Device Description

The **clue medical** is an handheld battery operated single-channel ECG recorder featuring four fixed electrodes on the back of the device, an ECG lead connector, an IrDA[1] interface and one single button to record and store up to ten ECG recordings with 30 seconds or two minutes duration. The stored ECG tests are processed into a printable Portable Document Format (pdf) that can be transmitted two ways. The pdf can be transmitted via IrDA to an IrDA capable local PC or printer. If the receiving device is not IrDA capable, an optional IrDA USB stick is provided with the **clue medical**. The pdf file can then be saved, sent, displayed or printed. Alternatively, the pdf can be transmitted via an IrDA capable cell phone directly to the Telovital server for storage.

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[1] IrDA refers to Infrared Data Association, a standard for communication between devices (such as computers, PDAs and mobile phones) over short distances using infrared signals. The Infrared Data Association (IrDA) defines physical specifications communications protocol standards for the short-range exchange of data over infrared light.

The **clue medical BASIC** is identical to the clue medical in design. The only difference is that the **clue medical BASIC** does not provide the added capability of sending the ECG data via cell phone directly to the Telovital server, it is only capable of IrDA transmission to a local PC or printer.

Performance Testing

The **clue medical** and **clue medical BASIC** have been tested to meet all of the following standards:

- IEC 60601-1, "Medical Electrical Equipment, General Requirements for Safety"
- IEC 60601-1-1, "Safety Requirements for Medical Electrical Systems"
- IEC 60601-1-2, "Part 1, General Requirements for Safety"
- IEC 60601-2-25, "Medical Electrical Equipment Part 2: Particular Requirements for the Safety of Electrocardiographs"
- IEC 60601-2-47, "Medical Electrical Equipment, Particular requirements for safety, including performance, for ambulatory electrocardiographic systems"

Electrode leadwires were found to be compliant to IEC 60601-1, subclause 56.3(c).

Technological Characteristics and Substantial Equivalence

The **clue medical** and **clue medical BASIC** are substantially equivalent to one or more of the predicate devices in design, measurement capability intended use and output format. Their design, measurement capability and output are equivalent to the previously cleared Sensor Mobile device (K050670) and Portable EC Scope (K072353). Their intended use is equivalent to the Omron HCG-801 Portable ECG Monitor (K060766). This premarket notification has described the characteristics of the **clue medical** and **clue medical BASIC** in sufficient detail to assure substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NOV 10 2008

Re: K082013
Trade Name: clue medical and clue medical BASIC Telemedical
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Codes: DPS, DXH
Dated: October 9, 2008
Received: October 10, 2008

Dear Ms. Herzog:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Section 4: Indications for Use Statement

510(k) Number: K082013

Device Name: **clue medical** and **clue medical BASIC**

Indications for Use:

The **clue medical** and **clue medical BASIC** are handheld, battery operated single channel electrocardiographs intended for recording and transmitting ECG data by patients who are concerned about their heart rhythm. The **clue medical** and **clue medical BASIC** allow the patient to record their ECG data into the device memory and transmit it for display by healthcare professionals.

Specifically, the **clue medical** and **clue medical BASIC** are intended for patients that are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:
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History of arrhythmia

The **clue medical** and **clue medical BASIC** ECG data is intended to be used by a licensed health care practitioner. These measurements are not intended for any specific clinical diagnosis. The clinical significance must be determined by the physician.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vickers

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082013